

AUG 15 2003

K032369  
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## Section 2 Summary

### 510(k) Summary of Safety and Effectiveness

Date: July 30, 2003

Submitter: GE Medical Systems *Information Technologies*  
8200 West Tower Avenue  
Milwaukee, WI 53223 USA

Contact Person: Diana M. Thorson  
Regulatory Affairs Specialist  
GE Medical Systems *Information Technologies*  
Phone: 714-247-4135  
Fax: 714-247-4155

Device: Trade Name: ApexPro Telemetry System

Common/Usual Name: Telemetry Monitoring System

Classification Names:

21 CFR 870.1025 Detector and Alarm, Arrhythmia

21 CFR 870.2910 Transmitters & Receivers, Physiological Signal, Radio Frequency

Predicate Device: K021325 ApexPro Telemetry System

Device Description: The ApexPro Telemetry System is composed of six major components:

- The patient worn data acquisition transmitters
- The receiver antenna system infrastructure
- The receivers
- The receiver subsystem
- A computer platform running the ApexPro Telemetry Application
- A computer platform running a central station application (which may be the same computer platform running the ApexPro Telemetry Application)

Intended Use: The ApexPro Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

The ApexPro Telemetry System is intended to be installed in the hospital or clinical environment in order to provide clinicians with patient physiological data, while allowing for patient mobility. These systems are typically deployed in sub acute care areas in hospitals or clinical sites where patient mobility can enhance the effectiveness of the medical procedures administered.

The physiological parameters monitored include ECG, non-invasive blood pressure and SpO<sub>2</sub>. The ApexPro Telemetry System is intended to provide ECG data via Ethernet to the computer platform for processing. The ApexPro is also intended to provide physiologic data over the Unity network to clinical information systems for display.

Technology: The ApexPro employs the same functional technology as the predicate devices. The system architecture has taken advantage of

improvements in signal processing technology as well as advances in RF component technologies to improve performance and level of integration.

Test Summary:

The ApexPro complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion:

The results of these measurements demonstrated that the ApexPro System is as safe, as effective, and performs as well as the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 15 2003

GE Medical Systems Information Technologies  
c/o Ms. Diana M. Thorson  
Regulatory Affairs Specialist  
8200 West Tower Avenue  
Milwaukee, WI 53223

Re: K032369  
Trade Name: ApexPro Telemetry System  
Regulation Number: 21 CFR 870.1025  
Regulation Name: Arrhythmia detector and alarm.  
Regulatory Class: Class III (three)  
Product Code: MHX  
Dated: July 30, 2003  
Received: August 1, 2003

Dear Ms. Thorson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

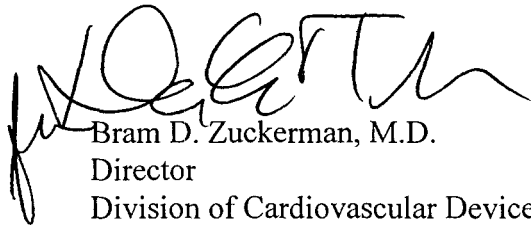
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

Page 2 – Ms. Diana M. Thorson

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over the printed name and title.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known):

510(k) filed on July 29, 2003

Device Name: ApexPro Telemetry System

Indications For Use:

The ApexPro Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

The ApexPro Telemetry System is intended to be installed in the hospital or clinical environment in order to provide clinicians with patient physiological data, while allowing for patient mobility. These systems are typically deployed in sub acute care areas in hospitals or clinical sites where patient mobility can enhance the effectiveness of the medical procedures administered.

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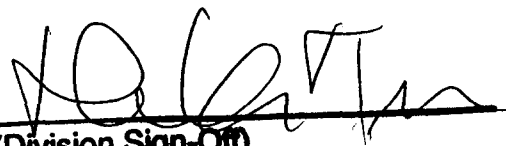
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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K032369